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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/079,416	02/22/2002	Oliver Yoa-Pu Hu	39297-174170	8467

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EXAMINER	
KIM, VICKIE Y	

ART UNIT	PAPER NUMBER
1614	9

DATE MAILED: 06/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/079,416	YOA-PU HU ET AL.
	Examiner	Art Unit
	Vickie Kim	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 10-32* is/are pending in the application.

4a) Of the above claim(s) *10-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 17-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Status of Application

1. Acknowledgement is made of amendment filed 03/18/2003 and supplement amendment filed 04/01/2003. Claims 3-9 has been canceled and new claims 17-32 has been added. Since there is no argument found in the applicant's response in addition to the scope changes made on the newly amended claims(paper no.8), the new ground of rejection is necessitated as follows wherein the examination is based on the elected claims 1-2 and 17-32.

2. Claims 1-2 and 10-32 are pending.

3. The elected claims 1-2 and 17-32 are presented for the examination and the non-elected claims 10-16 are withdrawn from the consideration.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 28-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Claims 28-29 recite "said dermal CYP1A inhibitor or said hepatic CYP1A" in line 1 in each claim respectively. Prior to these said limitations, "liver cytochrome P450 1A (CYP1A) inhibitor" is mentioned. Thus, there is insufficient antecedent basis for this limitation in the claim.

The claims 28-29 and its dependent claims 30-32 are properly included in this rejection.

b. Claim 30 recites "said liver CYP1A according to claim 28". However, claim 28 recites liver CYP1A inhibitor not liver CYP1A. Thus, there is insufficient antecedent basis for this limitation in the claim.

The claim 30 and its dependent claims 31-32 are properly included in this rejection.

4. Claims 18, 20-26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim 18 recites "cytochrome 450 1A enzymatic activity" and the claim 20 or 25 recites "a first-metabolism of a drug" or "conversion of a chemical into a carcinogen". However, it is not clear how these dependent claims are further limiting the subject matter of the previous claims and how these further limitations are affecting the scope of the subject matter of the previous claim 18, which is directed to a pharmaceutical composition comprising a compound such as α- or β- naphthoflavones. Thus, claims 18, 20, 25 and their dependent claims 21-24 and 26 are properly included in this rejection.

Claims 21-26 are also included in this rejection due to the same reason(supra). Claims 21-26 recite "a dermatological drug", "retinoid" "retinoic acid" "co-administration of said dermatological drug with said pharmaceutical composition" and "skin cancer caused by carcinogen", respectively. Since the dermatological drug is not included as

the part of the claimed composition, it is not clear how these dependent claims are further limiting the subject matter of the previous claims, that is the composition which contains the compound(e.g. α- or β- naphthoflavones) according to the claim 1 in this case. Thus, the limitations recited in the instant claims 21-26 are not clearly described how they are related to the structure of the subject matter claimed in previous claims, and thus, claims are indefinite. If said limitations are affecting the scope of the subject matter of the previous claims, applicant is advised to include the specific elements that indicate the relationship between said limitation and the subject matter of the previous claim. As stated in the instant specification, For instance, Said inhibitory activity is affected by the amount involved, applicant is advised include the amount required since the amount seems to be the critical element wherein said limitations have patentably weight since it affects the scope of the claims and properly further limiting the subject matter of the previous claims those are directed to a pharmaceutical composition containing a compound having CYP1A inhibitory activity in this case, the therapeutic effective amount should be specifically claimed if said inhibitory activity is variable depending on the amount used and this rejection would be obviated by doing so. For the reasons mentioned immediately above, the claims are properly included in this rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-2 and 27-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Guengerich et al(US 5,886,157).

Claims 1-2 and 27-29are directed to a dermal cytochrome P4501A (CYP1A) inhibitor or a liver cytochrome P4501A (CYP1A) inhibitor selected from various compounds such as α-naphthoflavone. Thus, claims are drawn to the compounds that are notoriously known compound in the art for decades, the claimed compound is not considered to be a patentably distinguished from the knowledge known in the art(see Merck manual, cited for evidentiary document but not for the prior art purpose because it is notoriously known in the art).

In any event, claims 1-2, 17-29 are clearly taught by the US'157.

US'157 teaches a cytochrome P450 1A(CYP1A) inhibitor, α-naphthoflavone, see especially claim 8. As I mentioned immediately above(supra), regardless to the teaching about CYP1A inhibitory activity of α-naphthoflavone, the claims are met by the cited reference because the claims are drawn to the compound and pharmaceutical composition containing the said compound. The compound (i.e. α-naphthoflavone) is well taught by the cited reference and thus, the claims are met by the cited reference.

It is noted that "a dermal or liver cytochrome P450 inhibitor" recited in the instant claims des not have patentable weight because it is considered as an inherent feature where the compound(i.e. α-naphthoflavone) inherently possesses dermal or liver cytochrome P450 inhibitory activity, see Ex parte Novistski, 26 USPQ 2d 1389. Applicant should be reminded that the biological and pharmacological activity of the

compound claimed would not affect the structure of the claimed subject matter (compound in this case), whereas the discovery of said activity of the claimed compound(old and well known) would be critical when the subject matter requires the said activity such as treatment or diagnostic assay. However, in this case, the subject matter is drawn to the compound not a treatment or other use. For instance, a dermal CYP1A and a liver CYP1A inhibitor are drawn to the same compound when α-naphthoflavone is selected as the said inhibitor, and not more than one patent can be given to the same compound(having utility) if the compound is the subject matter claimed. In this case, since the claimed subject matter is drawn to a compound that is already known for decades, the claimed compound such as α-naphthoflavone, therefore, can not be the patentably distinguished from the compound already known in the art.

Thus, the recitation "a dermal or liver cytochrome P450 inhibitor or inhibitory activity" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

All the critical elements are taught by cited reference and thus, all the claims 1-2 and 27-29 are anticipated by the cited reference.

3. Claims 1-2 and 17-29 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Shade et al (WO00/62769).

WO'769 teaches a compound(i.e. β-naphthoflavone) and a composition containing β- naphthoflavone. WO'769 further teaches a topical composition containing β- naphthoflavone as an effective active agent, see claims 1-2.

The instant claims 1-2 and 27-29 are drawn to a compound or a composition containing the said compound having dermal or liver cytochrome P4501A activity such as β-naphthoflavone. The instant claims 17-26 and 30-32 are drawn to a pharmaceutical composition containing the compound according to the claim 1 such as β- naphthoflavone. The instant claim 19 is specifically drawn to a topical composition comprising said compound such as β- naphthoflavone.

Since WO'769 teaches a topical composition containing β-naphthoflavone as an active agent, all the critical elements required by the instant claims are well taught by the cited reference and thus, not considered to be novel. For the very same reasons mentioned in earlier 102 rejection(supra), the claimed subject matter is not patentably distinguished over the prior art if the record.

As mentioned immediately above in this office action(supra), the limitations(i.e. dermal or liver CYP1A inhibitory activity, first-pass metabolism of a drug such as retinoid, conversion of a chemical into carcinogen, skin cancer caused by carcinogen) recited in the instant claims do not have patentable weight because it does not affect the scope of the claims, in the other words, it does not change the structure of the claimed subject matter because said limitations merely describe the intended use of the

claimed subject matter, for example, β- naphthoflavone or β- naphthoflavone containing composition, in this case.

All the claims are met by the cited reference and the properly included in this rejection.

Conclusion

4. No claims are allowed.

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vickie Kim whose telephone number is 703-305-1675. The examiner can normally be reached on Tuesday-Friday. If attempts to reach the

examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-3165 for regular communications and 703-746-3165 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Vickie Kim,
Patent examiner
August 29, 2003
Art unit 1614